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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,177	03/17/2004	Norman R. Wainwright	CHR-004	4155

51414 7590 07/03/2007

GOODWIN PROCTER LLP  
PATENT ADMINISTRATOR  
EXCHANGE PLACE  
BOSTON, MA 02109-2881

EXAMINER
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BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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07/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/803,177	WAINWRIGHT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nathan A. Bowers	1744	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Nathan Bowers. (3) Duncan Greenhalgh.  
(2) Norman Wainwright. (4) Gladys Corcoran.

Date of Interview: 27 June 2007.

Type: a)  Telephonic b)  Video Conference  
c)  Personal [copy given to: 1)  applicant 2)  applicant's representative]

Exhibit shown or demonstration conducted: d)  Yes e)  No.  
If Yes, brief description: cartridge of the invention was presented.

Claim(s) discussed: independent claims.


Identification of prior art discussed: Mahiou, Tanaka, Numazawa and Parce.

Agreement with respect to the claims f)  was reached. g)  was not reached. h)  N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
**GLADYS J. CORCORAN**  
**SUPERVISORY PATENT EXAMINER**

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants discussed the prior art made of record, and presented the cartridge of the invention and demonstrated how it functions during an assay. Applicant also discussed possible claim limitations involving the use of anti-flaking agents, positive control conduits, and a pumping mechanism. It appears that these limitations would overcome the prior art made of record (see attached claim amendments). A new search and consideration would be necessary to fully address any potential new limitations. Should the apparatus claims contain allowable subject matter, method claims containing all the limitations of the apparatus will be considered for rejoinder. It is suggested that Applicant presents arguments in the next response as to how the references are not combinable as discussed in the interview.

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Attachment  
to  
Interview  
Summary

**FOR DISCUSSION PURPOSES ONLY**

**Amendments to the Claims**

Claim 12 has been cancelled without prejudice. Claims 1, 7, 13, 14 and 79 have been amended. The following list of claims replaces all prior versions and lists of claims in the application.

What is claimed is:

1. (Currently Amended) A cartridge for determining the presence or amount of a microbial contaminant in a sample, the cartridge comprising:
  - (i) a housing defining a fluid inlet port, an optical cell, and a conduit having a fluid contacting surface for providing fluid flow communication between the fluid inlet port and the optical cell, ~~wherein the optical cell is located downstream of the conduit;~~ and
  - (ii) hemocyte lysate and an anti-flaking agent dried on a region of the fluid contacting surface of the conduit, so that when a sample is applied to the fluid inlet port, the sample traverses the region and solubilizes the hemocyte lysate during transport to the optical cell.
2. (Previously Presented) The cartridge of claim 1, further comprising a chromogenic substrate disposed on a second, different region of the fluid contacting surface.
3. (Previously Presented) The cartridge of claim 2 or 79, wherein the second region is located downstream of the first region.
4. (Previously Presented) The cartridge of claim 1 or 79, further comprising a preselected amount of an agent representative of the microbial contaminant disposed on the fluid contacting surface of the conduit.
5. (Original) The cartridge of claim 4, wherein the agent is disposed on the first region.

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6. (Original) The cartridge of claim 4, wherein the agent is a bacterial endotoxin or a (1→3)-β-D glucan.

7. (Currently Amended) A cartridge for determining the presence or amount of a microbial contaminant in a sample, the cartridge comprising:

(i) a housing defining

a first fluid inlet port, a first optical cell, and a first conduit having a fluid contacting surface for providing fluid flow communication between the first fluid inlet port and the first optical cell, and

a second fluid inlet port, a second optical cell, and a second conduit having a fluid contacting surface for providing fluid flow communication between the second fluid inlet port and the second optical cell;

(ii) a first hemocyte lysate dried on a first region of the fluid contacting surface of the first conduit, so that when a sample is applied to the first fluid inlet port, the sample traverses the region and solubilizes the first hemocyte lysate during transport to the first optical cell; and

(iii) a second hemocyte lysate dried on a first region of the fluid contacting surface of the second conduit, so that when sample is applied to the second fluid inlet port, the sample traverses the region and solubilizes the second hemocyte lysate during transport to the second optical cell, and

(iv) an agent representative of a microbial contaminant dried on the fluid contacting surface of the first conduit.

8. (Previously Presented) The cartridge of claim 7, further comprising a chromogenic substrate disposed on a second, different region of the fluid contacting surface of the first conduit.

9. (Previously Presented) The cartridge of claim 8, wherein the second region is located downstream of the first region.

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10. (Previously Presented) The cartridge of claim 8, further comprising a chromogenic substrate disposed on a second, different region of the fluid contacting surface of the second conduit.
11. (Previously Presented) The cartridge of claim 10, wherein the second region is located downstream of the first region.
12. (Cancelled)
13. (Currently Amended) The cartridge of claim ~~12~~ 7, wherein the agent is disposed on the first region.
14. (Currently Amended) The cartridge of claim ~~12~~ 7, wherein the agent is a bacterial endotoxin or a (1→3)-β-D glucan.
- 15-78. (Cancelled).
79. (Currently Amended) A cartridge for determining the presence or amount of a microbial contaminant in a sample, the cartridge comprising:
  - (i) a housing defining a fluid inlet port, an optical cell located downstream of the fluid inlet port, and a first conduit having a fluid contacting surface for providing fluid flow communication between the fluid inlet port and the optical cell, a pump port located downstream of the optical cell, and a conduit connecting the optical cell and the pump port;
  - (ii) a hemocyte lysate ~~disposed~~ dried on a first region of the fluid contacting surface of the first conduit; and
  - (iii) a chromogenic substrate ~~disposed~~ dried on a second, different region of the fluid contacting surface of the first conduit,wherein, when a sample is applied to the fluid inlet port, the sample traverses the first and second regions and solubilizes the hemocyte lysate and chromogenic substrate during transport to the optical cell.